



DEPARTMENT OF HEALTH & HUMAN SERVICES

COPY 3438

Public Health Service

T1405M

February 13, 1998

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 206-486-8788
FAX: 206-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-08

John A. Priddy, President
Richardson Labs., Inc.
3475 E. Commercial
Meridian, Idaho 83642

WARNING LETTER

Dear Mr. Priddy:

The Food and Drug Administration (FDA) obtained a sample of "ENERGIA" during a routine survey of the market place. The FDA has reviewed the label for "ENERGIA", lot 46235 EX06/98, which is repackaged and distributed by your firm. The results of the label review and laboratory analysis reveal that this product is misbranded within the meaning of section 403(a)(1) of the Food, Drug, and Cosmetic Act (the Act) in that the percent of "zinc" declared on the label is false and misleading because the product contains less than 80% of the declared amount of this nutrient. "ENERGIA" is also adulterated within the meaning of 402(b)(1) of the Act in that a valuable constituent, zinc, has been omitted in whole, or in part.

The above violations include nutrition labeling violations that concern certain new labeling requirements and are not meant to be an all inclusive list of deficiencies on your label. Other label violations could subject this dietary supplement to legal action. It is your responsibility to assure that all of your product is labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing within thirty (30) working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Your response should include copies of the revised labels. If corrective action cannot be completed within 30 working days, state the reason for this delay and the time within which the corrections will be completed.

Your reply should be addressed to: Food and Drug Administration, P.O. Box 3012, Bothell, WA 98041-3012, Attention: Janelle K. Main, Acting Compliance Officer.

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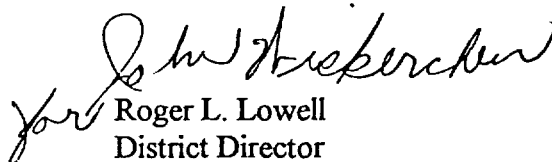
John A. Priddy, President

Richardson Labs., Inc.

Re: Warning Letter SEA 98-08

A copy of "A Food Labeling Guide" and applicable portions of the Act are enclosed for your review and information.

Sincerely,


for Roger L. Lowell
District Director

Enclosures

1. Section 402 and 403 of the Food, Drug, and Cosmetic Act
2. A Food Labeling Guide